SECTION 2: EXECUTIVE SUMMARY

AUG 14 2009

Intended Use:

VITEK® 2 Gram Negative Meropenem is designed for antimicrobial susceptibility testing of gram-negative microorganisms and is intended for use with the VITEK 2 and VITEK 2 Compact Systems as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents. VITEK 2 Gram Negative Meropenem is a quantitative test. Meropenem has been shown to be active against most isolates of the following microorganisms listed below according to the FDA label for the antimicrobial.

Active *in vitro* and in clinical infections:

Escherichia coli	*Citrobacter diversus*	*Pasteurella multocida*
Klebsiella pneumoniae,	*Citrobacter freundii*	*Proteus vulgaris*
Pseudomonas aeruginosa,	*Enterobacter cloacae*	*Salmonella* species
Proteus mirabilis,	*Hafnia alvei*	*Serratia marcescens*
Acinetobacter species	*Klebsiella oxytoca*	*Shigella* species
Aeromonas hydrophila	*Morganella morganii*	

The VITEK® 2 Antimicrobial Susceptibility Test (AST) is intended to be used with the VITEK® 2 and VITEK® 2 Compact Systems for the automated quantitative or qualitative susceptibility testing of isolated colonies for the most clinically significant aerobic gram-negative bacilli, *Staphylococcus spp.*, *Enterococcus spp.*, *Streptococcus agalactiae*, and *S. pneumoniae*.

Device Description:

The principle of the VITEK 2 AST cards is based on the microdilution minimum inhibitory concentration (MIC) technique reported by MacLowry and Marsh [1] and Gerlach [2]. The VITEK 2 AST card is essentially a miniaturized, abbreviated and automated version of the doubling dilution technique [3].

Each VITEK 2 AST card contains 64 wells. A control well which contains only microbiological culture media is resident on all cards. The remaining wells contain premeasured portions of a specific antibiotic combined with culture media. The bacterial isolate to be tested is diluted to a standardized concentration with 0.45 –0.5% saline before being used to rehydrate the antimicrobial medium within the card. The VITEK 2 System automatically fills, seals and places the card into the incubator/reader. The VITEK 2 Compact has a manual filling, sealing and loading operation. The VITEK 2 Systems monitor the growth of each well in the card over a defined period of time (up to 18 hours). At the completion of the incubation cycle, a report is generated that contains the MIC value along with the interpretive category result for each antibiotic contained on the card.

The MIC ranges, interpretive criteria and equivalent concentrations are as follows:

VITEK 2 AST-GN Meropenem	**Equivalent Standard Method Concentration by Efficacy in µg/ml**	**MIC Ranges and FDA Interpretive Criteria. MIC in µg/ml ***		
		S	I	R
Enterobacteriaceae, Acinetobacter spp., Pseudomonas aeruginosa	0.5, 2, 6, 12	**≤ 0.25 - 4**	**8**	**≥ 16**

* FDA category interpretation in bold-faced type.

S = Susceptible: Attainable levels in blood or tissue on usual usage, including oral administration when applicable.

I = Intermediate: "The "Intermediate" category implies clinical efficacy in body sites where the drugs are physiologically concentrated (e.g., quinolones and B-lactams in urine), or when a higher than normal dosage of drug can be used (e.g., B-lactams). The "Intermediate" category also includes a "buffer zone" which should prevent small, uncontrolled, technical factors from causing major discrepancies in interpretations, especially for drugs with narrow pharmacotoxicity margins." [4]

R = Resistant to usually achievable systemic concentrations.

Device Comparison Table:

The similarities and differences of the VITEK 2 Gram Negative Meropenem when compared to the predicate device, VITEK 2 Gram Negative Doripenem (K082346), are described in the following table.

Item	Device: VITEK 2 Gram Negative Meropenem	Predicate: VITEK 2 Gram Negative Doripenem (K082346)
Similarities		
Intended Use	VITEK® 2 Gram Negative Meropenem is designed for antimicrobial susceptibility testing of *Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Proteus mirabilis, Acinetobacter spp., Aeromonas hydrophila, Citrobacter diversus, Citrobacter freundii, Enterobacter cloacae, Hafnia alvei, Klebsiella oxytoca, Morganella morganii, Pasteurella multocida, Proteus vulgaris, Salmonella species, Serratia marcescens,* and *Shigella species*. VITEK 2 Gram Negative Meropenem is a quantitative test. It is intended for use with the VITEK® 2 and VITEK® 2 Compact Systems as a laboratory aid in the determination of in vitro susceptibility to antimicrobial agents.	VITEK® 2 Gram Negative Doripenem is designed for antimicrobial susceptibility testing of *Acinetobacter baumannii, Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa, Citrobacter freundii, Enterobacter cloacae, Enterobacter aerogenes, Klebsiella oxytoca, Serratia marcescens*. VITEK 2 Gram Negative Doripenem is a quantitative test. It is intended for use with the VITEK® 2 and VITEK® 2 Compact Systems as a laboratory aid in the determination of in vitro susceptibility to antimicrobial agents.
Test method	Automated Gram negative antimicrobial susceptibility test for use with the VITEK 2 and VITEK 2 Compact Systems (VITEK 2 Systems) to determine the *in vitro* susceptibility of gram-negative bacilli.	Same
Inoculum	Saline suspension of bacteria	Same

Item	Device: VITEK 2 Gram Negative Meropenem	Predicate: VITEK 2 Gram Negative Doripenem (K082346)
Differences		
Antimicrobial	Concentrations of the antimicrobial in the test wells of the VITEK 2 AST card and the analysis algorithms are unique for each specific antimicrobial.	Same

Discussion:

Both devices have similar Intended Use statements. The technological characteristics are similar but not identical. Both devices are designed for susceptibility testing of gram-negative bacilli on the VITEK 2 Systems and their technological characteristics are similar. The tests use the same base broth and are intended for use on the same VITEK 2 gram negative AST cards. The difference between the new device and the predicate device is related to the antibiotic. Concentrations of the antibiotic in the test wells and the analysis algorithms are unique for each specific antibiotic. In all other respects the two devices are identical.

The safety and effectiveness of VITEK 2 GN Meropenem is not impacted by the technology differences. Clinical studies were performed and demonstrate acceptable performance of VITEK 2 GN Meropenem. Performance is described in the following table.

Item	Device: VITEK 2 Gram Negative Meropenem	Predicate: VITEK 2 Gram Negative Doripenem (K082346)
Performance		
Clinical & Challenge Performance Data	EA = 97.6% CA = 96.8%	EA = 97.4% CA = 97.9%
Reproducibility	Best-case 99.6% Worst-case 99.6%	Best-case 99.2% Worst-case 90.6%
Quality Control	> 20 tests in range	> 20 tests in range
Meets Guidance Document Performance Requirements	Yes	Yes

Conclusion:

The analytical and clinical performance data presented in this submission support a substantial equivalence decision. The VITEK 2 Gram Negative Meropenem is substantially equivalent to the VITEK 2 Gram Negative Doripenem (K082346).

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Ms. Nancy Weaver
Associate Director, Regulatory Affairs
bioMérieux
595 Anglum Road
Hazelwood, MO 63042

AUG 1 4 2009

Re: k091899
Trade/Device Name: VITEK® 2 Gram Negative Meropenem (≤ 0.25 - ≥ 16 µg/ml)
Regulation Number: 21 CFR 866.1645
Regulation Name: Short-Term Antimicrobial Susceptibility Test System
Regulatory Class: Class II
Product Code: LON
Dated: June 22, 2009
Received: June 25, 2009

Dear Ms Weaver:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

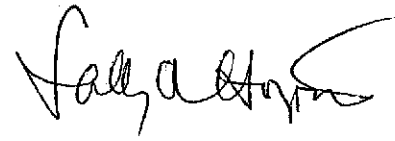
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091899

Device Name: VITEK® 2 Gram Negative Meropenem (≤ 0.25 – ≥ 16 µg/ml)

Indications For Use:

VITEK® 2 Gram Negative Meropenem is designed for antimicrobial susceptibility testing of gram-negative microorganisms and is intended for use with the VITEK 2 and VITEK 2 Compact Systems as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents. VITEK 2 Gram Negative Meropenem is a quantitative test. Meropenem has been shown to be active against most isolates of the following microorganisms listed below according to the FDA label for the antimicrobial.

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K091899